4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 56, and 812

[Docket Nos. FDA-2021-N-0286 and FDA-2019-N-2175]

RIN 0910-AI07 and 0910-AI08

Protection of Human Subjects and Institutional Review Boards, and Institutional Review Boards; Cooperative Research; Extension of Comment Period

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rules; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for two proposed rules that appeared in the *Federal Register* of September 28, 2022. In the proposed rule entitled "Protection of Human Subjects and Institutional Review Boards," FDA requested comments on proposed changes to its regulations regarding obtaining and documenting informed consent from research participants, and institutional review board membership and functions, including continuing review (Docket No. FDA-2021-N-0286). In the proposed rule entitled "Institutional Review Boards; Cooperative Research," FDA requested comment on a change to its regulations that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single institutional review board (IRB) for that portion of the research that is conducted in the United States, with some exceptions (Docket No. FDA-2019-N-2175). The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rules published in the *Federal Register* on September 28, 2022 (87 FR 58733 and 87 FR 58752). Either electronic or written comments must be submitted by December 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0286 for "Protection of Human Subjects and Institutional Review Boards" and/or Docket No. FDA-2019-N-2175 for "Institutional Review Boards; Cooperative Research." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: With regard to Docket No. FDA-2021-N-0286: Sheila Brown, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6563. With regard to Docket No. FDA-2019-N-2175: David Markert, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0752.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 28, 2022, FDA published two proposed rules with a 60-day comment period to request comments on proposed changes to its regulations regarding obtaining and documenting informed consent from research participants, and institutional review board membership and functions, including continuing review, as well as a change to its regulations that would require any institution located in the United States participating in FDA-regulated cooperative research to rely on approval by a single IRB for that portion of the research that is conducted in the United States, with some exceptions. Comments on the proposed rules will inform FDA's rulemaking to establish regulations for Protection of Human Subjects and Institutional Review Boards.

The Agency has received requests for a 60-day extension of the comment period for both proposed rules. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rules.

FDA has considered the requests and is extending the comment periods for the proposed rules for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: November 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-24689 Filed: 11/10/2022 8:45 am; Publication Date: 11/14/2022]